

OCT 29 2008

Exhibit#1

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland

Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: June 12, 2008

2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (Twin200)

3. Information for the 510(k) Cleared Device (Predicate Device):

- a. Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1), K073198, Microlife Intellectual Property GmbH.
- b. VP-2000/1000, K013434, Colin Corporation.

4. Device Description:

Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Office (Twin200) is designed to measure systolic and diastolic blood pressure, pulse rate, pulse pressure (PP) and mean arterial pressure (MAP) of an individual by using a non-invasive technique in which one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s). Our method to define systolic and diastolic pressure is similar to the auscultatory method but use two electronic pressure sensors rather than a stethoscope and mercury manometer. The sensors convert tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, pulse pressure (PP) and mean arterial pressure (MAP), which is a well - known technique in the market called the "oscillometric method".

The device has <<AUSCULTATION>>, <<1st VISIT>> and <<FOLLOW-UP>> measurement modes and has inflation pressure setting function, measurement intervals setting function etc. In additional, the device can be used in connection with your personal computer (PC) running the WatchBP Office software. The memory data can be transferred to the PC by connecting the monitor with the PC via bluetooth.

The <<AUSCULTATION>> mode is selected for blood pressure measurement of patients with arrhythmia, and, in need, to confirm if a patient is suitable for the oscillometric method using a digital blood pressure monitor. The subject device in this mode serves only as a pressure gauge. No oscillometric measurements will be taken and a mental note must be made of the systolic and diastolic values.

The <<1st VISIT>> mode is selected to complete a fully-automated three consecutive measurements on both arms simultaneously, the result of these three measurements are averaged to produce the 1st visit blood pressure measurement. This mode is helpful to determine the preferred measurement arm and reveal other cardiovascular risks for a patient's first office visit.

The <<FOLLOW-UP>> mode is selected to complete a fully-automated three consecutive measurements on the preferred arm, the result of these three measurements are averaged to produce the follow-up visit blood pressure measurement.

5. Intended Use:

The Microlife Upper Arm Blood Pressure Monitor, Model WatchBP Office (Twin200) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, pulse pressure (PP) and mean arterial pressure (MAP) of an adult individual by using a non-invasive oscillometric technique in which one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s).

The device can be used in connection with your personal computer (PC) running the WatchBP Office software. The memory data can be transferred to the PC by connecting the monitor with the PC via bluetooth.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The modified device model WatchBP Office (Twin200) and the predicate device model WatchBP Home (BP3MX1-1) use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff(s) is (are) inflated automatically, deflation rate is controlled by one (or two) factory set exhaust valve(s) and the deflation pressures are transferred via tubing to one (or two) sensor(s).

The solely differences between the two models are the additional features such as measuring location (single-arm or dual-arm), PP & MAP automatically calculation function. However, the differences do not affect the accuracy and normal use of this device.

Measuring on dual-arm and PP & MAP automatically calculation function are similar with what are used in predicate device VP-2000/1000, with 510(k) cleared number K013434.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (Twin200) in

the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

- a. Reliability Test - Storage test
- b. Reliability Test - Operating test
- c. Reliability Test - Vibration test
- d. Reliability Test - Drop test
- e. Reliability Test - Life test
- f. EMC Test
- g. IEC 60601-1 Safety Test
- h. Bluetooth Test
- i. FCC Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (Twin200) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

AAMI/ANSI SP-10 standard clinical testing was performed and the device met all applicable requirements of the standard.

9. Software information:

The subject device's software documentation is consistent with a moderate level of concern. We provided software documentation in accordance with the FDA's November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Moreover, our device requires the use of off-the-shelf software to operate the PC-link function and we have tested our OTC software in accordance with the FDA September 1999 document "Off-The-Shelf Software Use in Medical Device".

10. Conclusions:

We have demonstrated that there are no significant differences between the Microlife Upper Arm Automatic Digital Blood Pressure Monitor Model WatchBP Office (Twin200) and the predicate devices in terms of safety and effectiveness based on electrical, mechanical and environmental test results and the ANSI/AAMI Voluntary Standard, SP10: 2002 test results.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2008

Microlife Intellectual Property GmbH
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K082357

Trade/Device Name: Microlife Upper Arm Automatic Blood Pressure Monitor,
Model WatchBP Office (Twin200)

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: Class II (two)

Product Code: DXN

Dated: August 15, 2008

Received: August 18, 2008

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

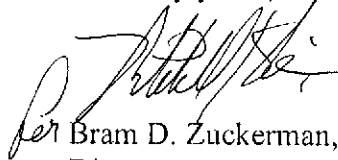
Page 2 – Ms. Susan D. Goldstein-Falk

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a horizontal line.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Page 1 of 1

510(k) Number (if known): _____

Device Name: Microlife Upper Arm Automatic Blood Pressure Monitor, Model
WatchBP Office (Twin200)

Indications For Use:

The Microlife Upper Arm Blood Pressure Monitor, Model WatchBP Office (Twin200) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, pulse pressure (PP) and mean arterial pressure (MAP) of an adult individual by using a non-invasive oscillometric technique in which one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s).

The device can be used in connection with your personal computer (PC) running the WatchBP Office software. The memory data can be transferred to the PC by connecting the monitor with the PC via bluetooth.

Prescription Use _____
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use X _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K082357